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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,068	08/02/2001	Thomas E. Clemente	UNL 2977.1	5827

321 7590 06/27/2003

SENNIGER POWERS LEAVITT AND ROEDEL  
ONE METROPOLITAN SQUARE  
16TH FLOOR  
ST LOUIS, MO 63102

EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

12

DATE MAILED: 06/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/921,068

Applicant(s)

CLEMENTE ET AL.

Examiner

Sean R McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 7-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Applicant's election with traverse of Group I claims 1-6 in Paper No. 11, filed 4/22/03 is acknowledged. The traversal is on the ground(s) that groups I and II are both drawn to methods of inhibiting where one group uses antisense and the other sense and assert, without evidence that the search of the methods would be coextensive and further assert that since the prior art regarding suppression of genes in eukaryotic cells is sufficiently sparse as to not create a burden. This is not found persuasive because a search of antisense would not necessarily find art directed to sense inhibitors and a search of sense inhibitors would not necessarily find antisense inhibitors. This logic is, for lack of a better term, "antisensical" since these compounds function by different mechanisms and possess different structures, for example. Applicant has not provided any evidence that the searches would be co-extensive and further have provided no evidence that the "prior art is sufficiently sparse". Applicant has not shown that the reasoning set forth in the restriction was in error or improper. In the amendment filed 3/28/03 new claims 41-66 would be members of Groups III and/or Group IV and are not included in the invention of Group I since these claims are drawn to transgenic plants, for example and for those reasons set forth in the Restriction requirement mailed 3/13/03.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-66 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

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linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Waterhouse et al [US 6,423,885 B1].

Waterhouse et al disclose in claims 1-14 a methods of reducing the phenotypic expression of a nucleic acid of interest by providing to the nucleus of a plant cell (eukaryotic cell) unpolyadenylated RNA (inhibits nucleus-to-cytoplasm transport) comprising a target specific nucleotide sequence produced by transcription from a chimeric DNA that comprises a promoter (which can be constitutive, inducible, or tissue specific, for example; see claims 8-11) operably linked to a sense sequence corresponding to the target nucleic acid and further comprising a self splicing ribozyme preceding a DNA region involved in 3' end formation.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waterhouse et al as applied to claims 1-5 above, and further in view of Taira et al.

Waterhouse et al is relied upon as above and additionally for the teachings at columns 10, 11, and 15 where it has been taught that the chimeric DNA more than one ribozyme (self cleaving) may be contained within the chimeric DNA of the invention such that more than one unpolyadenylated RNA molecules each targeting specific nucleotide sequence is generated and it has been taught that the target specific DNA region encoding the RNA with a target specific nucleotide sequence may be different.

Although clearly embraced within the scope of the disclosure, Waterhouse et al do not specify that the different RNAs containing different target specific sequences are targeted to different genes.

Taira et al have taught the use of constructs comprising self cleaving ribozymes to make several antisense based molecules from a vector. At column 6 it has been taught that the vectors may contain a number various concatameric units and that each concatameric unit can be targeted at different RNAs.

One in the art would clearly have combined the teachings of the prior art to make chimeric vectors as taught by Waterhouse that comprise different target specific RNAs where it has been specifically taught by Taira et al that one could clearly include inhibitory RNAs in concatameric constructs such as that taught by Taira and Waterhouse et al targeted to different RNA targets. Taira et al have suggested that the different RNAs could be targeted at sequences of virus that are known to be different in different strains, for example.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

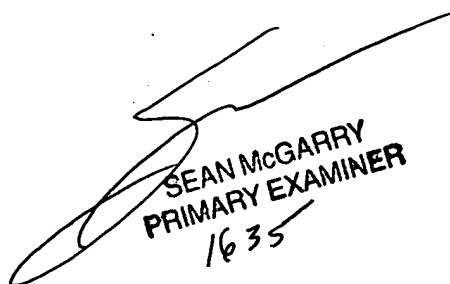
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM

June 26, 2003

  
SEAN MCGARRY  
PRIMARY EXAMINER  
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